REMARKS

Claims 1-21, 37-41, 45 and 46 are now pending in the application. Claims 45 and 46 are new and fully supported by the specification and drawings, as discussed below. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 102

Claims 37-39 and 41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Konieczynski et al (U.S. Pat. Pub. No. 2004/0127899). This rejection is respectfully traversed.

Konieczynski et al discloses a locking member 70 in the form of:

> ...a C-ring or expandable snap ring for placement around the groove 60 of the bone screws 40 and for capture within the seating groove 28 of the apertures 26. The locking members 70 are capable of expanding and contracting to snap into the groove 60 of the bone screws.

See p. 5, lines 1-7 of paragraph [0074] and FIGS. 1A-1C.

The locking ring of Konieczynski et al expands and contracts radially. The locking ring is not capable of expanding or contracting by rotational motion about the shaft axis of the bone screw because it is not designed for cam-actuated expansion, i.e., it does not include any cams in its inner opening. Rather, the locking member 70 is pushed into the groove 28 of the aperture of 26 of the bone plate before the bone fastener is inserted through the aperture. See p.5, lines 2-6 of paragraph [0080].

Further, to expand the locking ring 70 of Konieczynski et al:

> ... the surgeon can apply force to slide the bottom flange 54 of the screw 40 past the expandable locking member 70 until the head region 46 is nested within the locking member 70 aperture 26 as shown in FIG. 1C.

See paragraph [0080], line 11 (p. 5) to line 18 (page 6). In contrast, the head member of the present application expands and contracts by rotation relative to the shaft member, because it operates by cam action. See paragraphs [0046]-[0048] of the present application.

Accordingly, and regarding independent claim 37, Konieczynski et al fails to disclose, *inter alia*, an expandable head member carried by the shaft member and *being expandable by rotation about the shaft axis of the shaft member relative to the shaft member from a first circumferential position, in which the head member is not expanded to a second circumferential position in which the head member is expanded*, such that in the first position the expandable head member has a maximum diameter that is smaller than the first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter. Therefore, claim 37 is not anticipated by Konieczynski et al.

Claims 38, 39 and 41 ultimately depend from claim 37 and, at least for this reason, are not anticipated by Konieczynski et al. Claim 41 was amended to depend from claim 40 and is further discussed below in connection with the rejection of claim 40.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

In view of the obviousness rejections of the remaining claims, Applicants further submit that claim 37 and its dependent claims are also patentable over Konieczynski et al in view of Sutter et al, and refer Examiner to the discussion of the combination of these references below as equally applicable in relevant part to independent claim 37.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-21 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Konieczynski et al in view of Sutter et al (U.S. Pat. No. 4,388,921). This rejection is respectfully traversed.

As discussed above, Konieczynski et al discloses a locking member 70 in the form of a C-ring or expandable snap ring that is not capable of expanding or contracting by rotational motion about the shaft axis of the bone screw because it is not designed for cam-actuated expansion, i.e., it does not include any cams in its inner opening. Rather, the locking member 70 is pushed into the groove 28 of the aperture of 26 of the bone plate before the bone fastener is inserted through the aperture. See lines 2-6 of paragraph [0080]. Then the threaded portion of the bone screw is pushed through the locking member by applying *force to slide the bone screw past the expandable locking member until the head region of the screw is nested within the locking member.* See lines 12-18 of paragraph [0080] In contrast, the head member of the present application expands and contracts by rotation relative to the shaft member, because it operates by cam actuation. Accordingly, in spite of the assertions on page 4 of the Office Action, the locking ring of Konieczynski et al does not expand by and is not capable of expanding by rotation relative to the bone screw axis, for the simple reason that the locking ring and the bone screw do not operate by cam actuation. In fact, the Examiner acknowledges in the Office Action that Konieczynski et al lacks all the elements recited in claims 1021 and 40 relating to cam actuation. For these missing elements, the Office Action cites Sutter et al.

Setting aside for the moment whether Konieczynski et al can be properly combined with Sutter et al, Sutter et al also fails to provide the missing elements.

Sutter et al discloses a sleeve 211 inserted in a clearance hole 207a. The sleeve has an outer surface coaxial with axis 217 of the clearance hole. The sleeve has an opening 211c with an inner axis 219 displaced in relation to the axis 217 of the hole and coinciding with the axis 219 of the screw 209. The opening has a conical surface 211d and for slots 211e. The screw 209 includes a head 209b which is convex and shaped as a spherical zone designed to engage the conical surface 211d and serve as an expander because of the conical shape of the opening which has a *longitudinally* decreasing diameter. The conical surface 211 and the spherical zone 209c of the head 209b of the screw 209 have *constant curvature* at any location of their mutual engagement. See FIG. 15 and column 9, lines 9-40. The sleeve expands because the head 209 has bigger diameter than the diameter of the cone at any location of contact, but at each location, these diameters are constant and not circumferentially variable. Further, in each position of engagement the inner circumference of the sleeve mates and is aligned with the outer circumference of the bone screw. This fact is not changed just because the axes 217 and 219 do not coincide.

Regarding the combinability of Konieczynski et al with Sutter et al, Applicants respectfully submit that the locking ring of Konieczynski et al is designed to be a C-ring or a snap ring and accordingly cannot be functionally replaced with a sleeve having four longitudinal slots and a conical inner surface, as Sutter et al teaches. In other words, the teachings of Konieczynski et al and Sutter et al teach away from each other, and even if they are combined from a heap of random elements abstracted therefrom, the

structure of the claimed devices as claimed in the present application cannot be reconstructed from this heap.

Accordingly, and regarding independent claim 1, Konieczynski et al and Sutter et al, either individually or in combination, fail to disclose, *inter alia*, a shaft member with an outer cam in the form of a continuous curve of continuous slope and *circumferentially* variable radius, and a head member defining a circumferential inner cam in the form of a continuous curve of continuous slope and *circumferentially* variable radius in a plane perpendicular to the longitudinal axis of the shaft member, the outer cam circumferentially mating with the inner cam of the head member *in a position of cam alignment*, such that upon rotation of the head member relative to the shaft member *to a position of cam misalignment*, the head member radially expands to prevent back out of the shaft member relative to the bone fixation plate. Therefore, claim 1 is patentable over Konieczynski et al in view of Sutter et al.

Claims 2-16 ultimately depend from claim 1 and, at least for this reason, are also patentable over Konieczynski et al in view of Sutter et al. Further, and regarding claim 2, Konieczynski et al and Sutter et al fail to disclose a lobe defined as a segment radially offset from the internal surface of the head member. Further, and regarding claim 3, Konieczynski et al and Sutter et al fail to disclose a plurality of lobes interconnected by variable radius curves. Therefore, claims 2-16 are also patentable over Konieczynski et al in view of Sutter et al.

Similarly, and regarding independent claim 17, Konieczynski et al and Sutter et al, either individually or in combination, fail to disclose, *inter alia*, a head member having an internal circumferential surface in the form of a *circumferentially multi-radius*

continuously curved inner surface with a head cam lobe circumferentially mating with an outer shaft cam lobe *in a position of cam alignment,* such that upon rotation of the head member relative to the shaft member, *the shaft cam lobe rotates out of alignment relative to the head cam lobe* forcing the head member to expand radially to prevent back out. Therefore, claim 17 is patentable over Konieczynski et al in view of Sutter et al.

Claims 18-21 ultimately depend from claim 17 and, at least for this reason, are also patentable over Konieczynski et al in view of Sutter et al. Further, and regarding claim 19, and claim 20 that depends from claim 19, Konieczynski et al and Sutter et al fail to disclose a plurality of lobes interconnected by variable radius curves. Therefore, claims 18-21 are patentable over Konieczynski et al in view of Sutter et al.

Claim 40 depends from 37, which, as discussed above, is not anticipated by Konieczynski et al. Further, and as discussed above in connection with claims 1 and 17, Konieczynski et al and Sutter et al, either individually or in combination, fail to disclose, *inter alia*, that the cams of the head member and shaft member are aligned in a first circumferential position and *misaligned* in a second circumferential position and that each cam has a *circumferentially* variable radius. Therefore, claim 40 is patentable over Konieczynski et al in view of Sutter et al.

Claim 41 depends from claim 40 and, at least for this reason, is also patentable over Konieczynski et al in view of Sutter et al. Further, Konieczynski et al and Sutter et al fail to disclose a plurality of lobes interconnected by variable-radius curves.

Reconsideration and withdrawal of the rejections of claims 1-21, 40 and 41 is respectfully requested.

NEW CLAIMS

Claims 45 and 46 are new and fully supported by the specification and drawings. Support can be found, for example, in FIGS. 3-5, 13 and 15 and paragraphs [0040]-[0043], [0047] and [0048]. Accordingly, no new matter is added. Regarding independent claim 45, Konieczynski et al and Sutter et al, either individually or in combination, fail to disclose, inter alia, an outer shaft cam curve defining a plurality of cam lobes interconnected with curves of variable radius and an expandable head member having an inner opening defining an inner head cam curve, the inner head cam curve circumferentially mating and aligned with the outer shaft cam curve in an unexpanded configuration, the inner head cam curve circumferentially misaligned relative to the outer shaft cam curve in an expanded configuration. Claim 46 depends from claim 45. Accordingly, claims 45 and 46 are patentable over Konieczynski et al and Sutter et al.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner

believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: June 6, 2007

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